UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,079	01/18/2006	**Jun Keun Chang**	CHANG216	3911

1444 7590 11/03/2010

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
KINGAN, TIMOTHY G	
ART UNIT	**PAPER NUMBER**
1772	

MAIL DATE	DELIVERY MODE
11/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,079	CHANG ET AL.	
	Examiner	Art Unit	
	TIMOTHY G. KINGAN	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5 and 7-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4, 5 and 7-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/29/2010 has been entered.

Response to Arguments

1. Applicant's argues that Qui does not teach the use of a first substrate with a recess on a surface, such element is known in the microfluidics art for defining a channel or chamber when fixed to a planar second substrate; further, devices so configured include those used for optical monitoring of events or particles in channels or chambers. One of ordinary skill in the art would recognize structural configurations of counting chambers comprising those defined by recesses and those defined by adhesive, with or without polymer film, as two species amongst a limited set capable of serving equivalent functions.

2. With regard to applicant's argument concerning the composition of the lower substrate and the use of positive grid lines fabricated on a plastic substrate by injection molding, such elements are known in the art and new references teaching such elements are cited below.

3. With regard to the element of a unitary upper substrate comprising a recess, such element is known in the art and was cited in the previous office action.

4. The applicant is advised that the Supreme Court recently clarified that a claim can be proved obvious merely by showing that the combination of known elements was obvious to try. In this regard, the Supreme Court explained that, "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has a good reason to pursue the known options within his or her technical grasp." An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. See *KSR Int 'l v. Teleflex Inc.,* 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007). In the instant application, the elements claimed are all known in the art of cell counting and/or optical analysis in microfluidic devices, and applicant does not provide evidence of unexpected results from the claimed combination.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. **Claims 1, 2, 4, 5 and 7-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over J. Qiu, U.S. Patent Application Publication 2004/0145805 (herein after Qiu; effective filing date 01/16/2003) in view of C.L. Hansen et al., U.S. Patent Application Publication 2003/0061687 (herein after Hansen), R. Nagle and C.B. Kennedy, U.S. Patent Application Publication 2002/0092973 (herein after Nagle) and V.C. Mitchell, U.S. Patent 4,997,266 (herein after Mitchell).

For Claims 1, 2 and 4, Qiu teaches a unitary device for counting cells (fine particles) comprising a top part, a connection part and a base part, a counting chamber with a grid of microscopic lines to define a counting area, the connection layer bonding the top part and the base part (abstract), further comprising two ports **22** for sample application in the top substrate and two ports **24** for air escape ([0016], [0035]; Fig. 1b) (upper substrate comprises a discharge hole), the top part made of a film or sheet of plastic or glass [0038] (transparent upper substrate) and the base part (lower substrate) providing optical clarity to permit focus under the field of view of an optical microscope [0048] (transparent lower substrate; area of the fill chamber is transparent). Qiu further teaches that the top part and base part (upper and lower substrates may be bound directly to one another by an adhesive to form an integrated body, the space formed thereby defining the counting chamber of a predetermined height ([0043] and [0042]).

Qui does not teach an upper substrate comprising a recess formed in its bottom surface. However, substrates with such recesses are known in the art for defining channels or chambers. Hansen teaches microfluidic devices comprising elastomeric layers formed on a machined mold to produce an upper substrate **24** with a recess in

the bottom surface ([0123], Fig. 6, **21**), which, when sealed to a planar substrate **14**, forms a flow channel **30** ([128], Fig. 7B) (a unitary upper substrate comprising a recess in a bottom surface). That such manner of forming channels may be employed in optical detection is also known in the art. Nagle teaches a microfluidic device with integrated optical elements (title), the device comprising a planar substrate **110** (transparent unitary substrate; equivalent to applicant's upper substrate) with a groove or depression **114** (a recess on one surface forming a fill chamber) which, when fixed to a second planar substrate **102** forms a channel/chamber permitting optical detection ([0022], Figs. 2 and 4). It would have been obvious to one of ordinary skill in the art to use structural configurations of counting chambers comprising substrates with recesses fixed to planar substrates, according to the teachings of Hansen and Nagle, as an alternative to the use of a film stencil with adhesive or adhesive alone, amongst a small set of species for defining a counting chamber in the device of Qui, in order to provide the advantage associated with an elastomeric structure that may be peeled up, washed (for instance, free of particles) and re-used, according to the teaching of Hansen [0129].

While Qiu teaches that either the top substrate or the base part (upper or lower substrate) may contain precisely spaced lines in a grid pattern, which may be produced in substrate material by hot stamping or embossing [0053] to create positive grids (e.g., Fig. 3(d)) on either the top or bottom substrate (claims 2 and 4), including the upper surface of the bottom substrate (claim 5), the provisional application discloses formation of such grids only on the top substrate (60/440364, p. 2). Mitchell teaches an examination slide grid system (title) for counting suspended particles or cells (col 1,

lines 31-32) comprising an optical quality plastic slide with a grid system on the floor **16** of the examination chamber, the grid system incorporated in the mold for fabrication (col 1, lines 52-62; col 3, lines 60-62) (a lower substrate made of plastic wherein fine lattice patterns are formed on the upper surface of the lower substrate by molding). Further, examiner notes that conventional hemacytometers place grid lines on the upper surface of a transparent lower substrate, that, when lines are formed by etching, result in a lattice pattern comprising a positive grid between etched grooves. It would have been obvious to one of ordinary skill in the art to use the positive grid system on the upper surface of the lower substrate, according to the teaching of Mitchell and conventionally used in hemocytometers, in the device of Qiu, in order to provide for grid lines in close proximity to cells that may rest on the upper surface of the lower substrate, thereby improving imaging owing to the proximity of the planes of focus for cells and grid lines, as well as to provide a capture zone for improving the formation of an image owing to the reduction in movement associated with cells floating in medium.

With regard to the element of grids formed by injection molding, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be

rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (MPEP 2112.01). Here, examiner asserts that a substrate with grid lines made "molding", according to the teaching of Mitchell, cannot be distinguished from applicant's substrate with grid lines produced by "injection molding".

For Claim 5, Qiu teaches that the total thickness of the space (formed by a connecting layer or an adhesive) is chosen to be suitable for different sized cells and can range from 0.01 mm to 5 mm, preferably between 0.02 mm to 1 mm).

For Claim 7, Qiu, Hansen, Nagle and Mitchell do not teach an indicative member on the upper substrate. It would have been obvious to one of ordinary skill in the art to place an indicative member on the upper substrate in order to facilitate coarse positioning of the counting chamber, and the lattice therein, the fine markings of which may otherwise be difficult to locate in a method of counting involving microscopy.

For Claim 8, Qiu teaches that the base part (lower substrate) may be fabricated from any transparent plastic sheet [0049].

For Claim 9, Qiu teaches that biological solutions suitable for use in cell counting microscopic particles include blood or cell culture [0005].

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY G. KINGAN whose telephone number is

(571)270-3720. The examiner can normally be reached on Monday-Friday, 8:30 A.M. to 5:00 P.M., E.S.T..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, In Suk Bullock can be reached on 571 272-5954. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TGK

/In Suk Bullock/
Supervisory Patent Examiner, Art Unit 1772